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ABSTRACT

Guidelines (established at the Syracuse Development Center) for conducting human research with institutionalized mentally retarded persons are discussed, particularly in relation to research in behavior modification. After a literature review, the five step procedure suggested by the Center is listed with such steps as submitting a proposal which identifies benefits and risks and obtaining written informed consent from the subjects, parents, or legal guardians. The difficulty of determining what constitutes subject informed consent and the possibility that parents or guardians may not always be acting in the best interests of their children has led to guidelines requiring (1) that permission also be obtained from the facility's Human Rights Committee and (2) that no S ever be forced to participate in a study even though appropriate consent was obtained. Other issues addressed include obtaining consent from no-treatment control subjects, the use of aversive conditioning methods, and fear research. Appended are forms required at the Center in the research approval process. (PHS)

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Ethical Standards And Behavior Modification Research In Institutions For Retarded People

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Ethical Standards and Behavior Modification Research In Institutions for Retarded People

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In a recent article, Friedman (1977) made the statement that mentally retarded people have traditionally been treated as second-class citizens within our legal system. In the past, and to some extent today, mentally retarded persons have been denied or have had infringements on a wide variety of basic rights - including the right to privacy, the right to travel, the right to medical treatment, the right to sexual expression, the right to education, the right to enter into a contractual agreement, the right to vote, the right to secure suitable housing, and so forth. Friedman (1977) further implies that discrimination against the mentally retarded has been so widespread and pervasive that these people may be deprived of "virtually all of their legal rights" (p. 50).

Because of the obvious injustices to which mentally retarded persons have been exposed, as well as the increasing activism of human rights advocacy groups, we are beginning to find much more literature published (e.g., Friedman, 1977; Heads, 1978; Kazdin, 1975, 1977; McCann, 1977; National Association for Retarded Citizens, 1976; Repp, 1978; Roos and McCann, 1977, and cases brought to court (e.g. Anderson v. City of Shoreview, 1975; Bartley v. Kremens, 1975; Dixon v. Attorney General, 1971; N.Y. State Association for Retarded Children, Inc. v. Carey, 1975; O'Connor v. Donaldson, 1975; Pennsylvania Association for Retarded Children v. Commonwealth of Pennsylvania, 1971; Wyatt v. Stickney, 1972) regarding the rights of mentally retarded people. One specific area of this human rights movement which has only recently

gained increasing interest pertains to the protection of the rights of mentally retarded persons who participate in experimentation. Concern with this area emerged, in part, from two relatively recent landmark court cases. In the Wyatt v. Stickney opinion of the Fifth Circuit Court of Appeals, given in April, 1972, the court sought to establish a resident advocacy committee, called a Human Rights Committee, which "will have review of all research proposals and all rehabilitation programs, to insure the dignity and human rights of residents." Similarly, the Willowbrook consent decree (May, 1975) absolutely forbid seclusion, corporal punishment, medical experimentation, and routine use of restraints, and recommended that each institution establish a seven member resident advocacy committee to ensure and protect the human rights of residents.

Interestingly, our present concern with protecting people who participate in research is not, in fact, recent. As Stuart (1978) points out, The Nuremberg Code (1946) was specifically concerned with protection of the right of informed consent in experimentation. It consisted of the following criteria for granting informed consent: (1) the person should be legally able to give consent, (2) consent must be granted without duress, coercion, or deceit, and (3) the person must be provided with sufficient knowledge concerning the research project in order that s/he understands all possible anticipated consequences regarding his/her participation in the research (Stuart, 1978). The ease with which informed consent is obtained, however, may not necessarily be related to whether the potential participant is, in fact, informed. For example, Stuart (1978) found that approximately 14% of the college students who were to participate in a proposed study, about which they were completely informed, cited upon questioning that they knew that electric shock was going to be used in the study,

and 18% of the students gave incorrect answers concerning the proposed study on the objective portion of the consent form. Gray (1975) found that 39% of the subjects who participated in a drug study did not reflect their understanding of the research project, even though they were informed about the nature of the drug study and also signed the consent form. If "normal" intelligence people have difficulty understanding the research in which they have signed their consent, what can we as researchers expect of mentally retarded persons?

In this paper, I would like to outline some of the human research guidelines we have worked out at the Syracuse Developmental Center, one of the New York State residential centers for retarded persons, and discuss how it applies to research in behavior modification.[1] Our Research Review Committee sees as its purpose "to stimulate, evaluate for approval, and facilitate quality research in the area of mental retardation by agency staff and/or professionals from the community. The policies and procedures which we developed was a joint effort by the Research Review Committee, under the chairpersonship of Carl E. Meuhlberger, Ed.D.

The following procedure has been suggested to any person who plans to conduct research at the Syracuse Developmental Center, Syracuse, New York[2]:

(1) A proposal should be submitted to the chairperson in which the purpose and hypotheses are clearly stated, and the methodology is completely detailed. The potential benefits and risks involved are also outlined.

(2) A signed Principal Investigator's Assurance form should be submitted in which the principal investigator assures the committee that s/he will respect the rights and welfare of the research subjects and will conduct the research in an ethical and

responsible manner (see form in Appendix).

(3) The proposal is then discussed among members of the committee. If members of the committee have questions about the proposal, the principal investigator will be asked to come to a meeting to answer questions.

(4) In order for a vote to occur, 5 out of 8 members of the committee must be present, and there must be at least a four-fifths consensus of approval.

(5) Upon approval, the principal investigator is informed and s/he then must obtain the written informed consent of all prospective research subjects before the study is to begin. For clients under 18 years of age, written informed consent must be obtained from the parents or legal guardian. In those cases where there is no legal guardian or parent, the decision to allow a minor to participate will be deferred to the facilities Director. For those clients over 18 years of age, they may give their signed consent directly - assuming they are judged by their Chief of Service to be competent to make that decision. In cases where the client is not competent, the facility's Director will be asked to make the decision regarding the client's research participation.

In those cases where the investigator only requires access to client records and for demographic data, where there is no experimental manipulation or need to use such clinical information as psychological test results, informed consent will generally not be required. The principal investigator, however, must assure the committee that all data collected from the records will <u>not</u>

be identifiable.

The investigator must also provide the committee with periodic progress reports on the research project, provide a final report on the project to the committee, and also make available a copy of the final report to the client, parent, guardian, etc.

In terms of behavior modification research, as well as any other research which is proposed, one question which immediately arises is what constitutes subject informed consent (see Appendix for consent form)? Even though the prospective research subject is told about the experiment, the potential discomforts and risks, the expected benefits, and the freedom to withdraw from participation at any time, and s/he signs the consent form, does this necessarily mean that the client fully understood what was said and what they signed? Clearly, from Stuart (1978) and Gray's (1975) research, we can question the validity of the informed consent notion. Moreover, what should be done in the case of incompetent prospective research subjects? For example, we obviously need to conduct research in the area of the severely retarded, and it is this population which most likely is not competent to give informed consent. Who should then provide the consent for these severely handicapped people? If the person is under 18 years of age, we might answer by saying that his/her parent or guardian can give the consent, but recent court decisions (e.g., Bartley v. Kremens, 1975; J. L. v. Parham, 1976) suggest that at least in terms of commitment practices, parents and guardians may not always be acting in the best interest of their children. Consequently, some parents or guardians may not also be acting in the best interest of their child by signing a consent form for their child's participation in research.

Obviously, the researcher has fulfilled his/her ethical responsibility

by obtaining the signed consent form from the parent or guardian, but it seems that another decision body, the facility's Human Rights Committee, should also decide if they feel it is harmful or potentially destructive or degrading for the particular child to participate in the research project. This same client advocacy committee could also be used for those incompetent persons over 18 years of age who do not have a legal guardian. In addition, under no conditions could a researcher be permitted to force someone to participate in a study at any time even though appropriate consent was obtained. This would especially allow nonverbal research subjects the opportunity to motorically express their right to refuse or withdraw from the research project. If the competency of the prospective research subjects can not be determined by the Research Review Committee and/or the Human Rights Committee, these committees could, as Stuart (1978) suggests, require the experimenter to objectively demonstrate that the subjects do fully comprehend the purpose, benefits, and potential risks of their involvement in the study. If a researcher was to proceed otherwise, and assume the validity of a signed consent by a person of questionable competence, s/he would, as Goldiamond states, "...face the same problems in a court of law as [would] a car salesman who proceeds likewise..." (p. 184).

Another question which arises from these research guidelines is what do you do with the no-treatment control subjects? For example, should a researcher obtain consent from those prospective subjects who will be in the control group conditions? In New York State, the question appears to have been answered - at least temporarily - for those researchers who conduct experiments in New York State facilities. According to a Directive (1977) from the New York State Department of Mental Hygiene, any "investigative, non-therapeutic research in which there is no intent or expectation

of treating an illness from which the client is suffering, or in which the client is a normal control who is not suffering from an illness but who volunteers to participate for the potential benefit of others" will be considered to be "at risk", and therefore informed written consent must be obtained.

A third question which arises pertains to aversive conditioning. What is not clear yet from the recent State guidelines or from the AAMD or NIMH guidelines is the conditions under which aversive conditioning research will be permitted with retarded persons. For example, does a researcher have to first demonstrate that no positive reinforcement procedure has been successful with a particular person before s/he can involve that subject in a study using aversive stimuli. In New York State, it is specifically stated as policy that "electrical shock shall not be used with the developmentally disabled" (New York State, 1977, p. 1). It is not clear, however, if this policy also pertains to the conduct of research on such behavior problems as self-injurious behavior. For example, could someone conduct research comparing the relative effectiveness and efficiency of contingent aversive electric shock, time-out, reinforcement of incompatible behaviors (dro), and responsive cost on the reduction of self-injurious behavior in severely retarded children? Clarification seems necessary here.

Another concern pertaining to these guidelines involves fear research. If, for example, we wished to study the efficacy of various fear reduction methods (Morris, 1975) on the control of phobic reactions in mentally retarded adults, would we be permitted to expose these people to the object(s) that they fear - and thus place them in a potentially threatening and/or harmful situation? Most guidelines talk about aversive procedures, but say nothing about exposing subjects to those stimuli that they fear in

order to help them overcome the fear.

Although these and other research ethics questions concerning behavior modification experimentation, and research in general, with retarded persons have not been fully answered at the local, state, or federal level, we as a profession have certainly taken tremendous strides in the last three years in attempting to protect the rights and welfare of those subjects who participate in our research. But, more discussion and debate at various decision making levels is needed to make sure that our prospective research subjects are protected from harm, respected, and viewed with dignity. The resulting guidelines for applied research in mental retardation may increase greatly the amount of time necessary to carry out and complete a particular research project, and may even limit the type of research which will be permitted in a particular facility, as well as restrict the population on which research can be conducted. It may even be decided that due to the demand characteristics and inherent coercive nature of a residential treatment facility, few, if any, residents can become prospective research subjects because they can not freely volunteer their consent to participate (Heads, 1978). The resulting benefits of these research ethics, however, may finally ensure that mentally retarded people will not be treated as second-class citizens, and that they - as any other research participant or nonparticipant in our society - must have their rights protected at all costs.

Footnotes

1 The research policy at the Syracuse Developmental Center was developed by the Research Review Committee. The committee consists of Dr. Carl E. Muehlberger (chairperson), Mr. Leonard Slosberg, Mr. Charles Soper, Dr. Theodore DiBuono, Dr. Stephen Driscoll, Mrs. Ann Vaquero, Dr. Richard J. Morris, Mr. William Morgan, Dr. Young S. Lee. The research policy which has been developed follows the Policies and Procedures for Mental Retardation manual of the New York State Department of Mental Hygiene.

2 The research policy presented here is an abridged version of the Policies and Procedures Statement of the Research Review Committee of the Syracuse Developmental Center. A copy of the unabridged policy is available from the author or from Dr. Carl E. Meuhlberger, Director, Staff Development, Syracuse Developmental Center, 800 South Wilbur Ave., Syracuse, New York 13201.

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App.4

PRINCIPAL INVESTIGATOR'S OR PROJECT DIRECTOR'S ASSURANCE

I, the undersigned, as the Principal Investigator or Project Director of the project entitled _____ do assure the Research Review Committee of _____ that:

1) I or my designated representative will obtain a written informed consent form from all participants in this study, or from their legal guardians or representatives, except where the Committee has determined that such consent is not required.

2) In making public any oral or written report concerning this study, I will take every precaution to protect the right to privacy of all subjects involved in it. I will not disclose the identity of any individual subject without his permission.

3) I will give prime consideration to the rights and welfare of all subjects in this study, and should the physical or mental health of the subjects be affected adversely by any procedures connected with this study, then any such procedures will immediately be suspended, and the circumstances will be reported to the Research Review Committee and to the Director of Research or Facility Director.

4) In my judgment this project conforms to all ethical requirements. Any aspects of this study which might appear to be questionable as the study progresses or evolves I will immediately bring to the attention of the Committee.

5) I fully understand and am aware of the conflict of interest regulations of the Department of Mental Hygiene and the State of New York and assure the Research Review Committee and the Director of Research or Facility Director that not only is there no actual conflict of interest, but there is nothing which might be questioned as a conflict of interest involving this project in relation to any other activities in which I am or will be engaged. If at any time there appears to be developing any such conflict of interest involving this project, then I obligate myself to bring this to the attention of the Research Review Committee.

_____ Date

_____ Principal Investigator or Project Director

App.3

REQUEST TO THE RESEARCH REVIEW COMMITTEE FOR REVIEW OF A PROPOSAL INVOLVING AN EXPERIMENTAL DRUG OR TREATMENT PROCEDURE

A. In accordance with applicable policies of the Department of Mental Hygiene, the Department of Health, Education and Welfare, and the Food and Drug Administration, you are requested to review the following proposal involving an experimental drug or treatment procedure to ensure that (1) the rights and welfare of the subjects are adequately protected, (2) that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained, and (3) that informed consent is to be obtained by methods that are adequate and appropriate. You are further requested to provide continuing review of this project, if approved, in accordance with the above policies.

1. Aim of procedure _____

_____

_____

_____

2. Material to be used _____

_____

_____

_____

3. Potential benefits _____

_____

_____

_____

4. Potential risks _____

_____

_____

_____

5. Protocol No. and Title _____

_____

Supporting documents and information are enclosed.

_____ Date

_____ Name of Investigator

B. Research Review Committee Action

Approved _____ Disapproved _____

Restrictions of Comments _____

_____

_____

_____ Date

_____ Chairman of Committee

C. Director of the Facility

Approved _____ Disapproved _____

_____ Date

_____ Director

N.Y.S. Department of Mental Hygiene	Date Issued	T.L.	Page	Item No.
DIRECTIVE	5/77	77-1	6 of 6	5.2.9
Policies and Procedures for Mental Retardation	Function: Client Protection			
	Subject: Client Rights			
Office of Primary Interest	Issuing Office: T.A.U.	Topic: Addendum B - Informed Consent for Client Participation in Research		

FORM FOR INFORMED CONSENT

Title of Project: _____

Drugs and/or Procedures Involved: _____

_____

_____

Benefits Expected: _____

_____

_____

Possible Risks Involved: _____

_____

I, _____, agree to participate in the above described research project, the nature and possible complications of which have been explained to me.

I also consent that any audio, visual, or psychological test data collected as a result of my participation in this project may be utilized for educational and/or scientific purposes either at _____ _____ or other scientific or educational establishments.

I have received assurance that all possible efforts will be made to otherwise preserve my anonymity in the use of this material.

I have received assurance that I may withdraw from participation at any time.

I further understand that my legal rights, regarding negligence and the liability of the facility or its agents, are not waived.

_____ _____

Date Signature of Research Subject

WITNESSED:

_____ (Other than researcher)

CERTIFICATION REGARDING INFORMED CONSENT

TO: Facility Research Review Committee

RE: Informed Consent Elements

This is to testify that the subject in agreeing to participate in the Research Project known as _____, has had explained the following basic elements:

1. A fair explanation of the procedures to be followed, including an identification of those which are experimental.

2. A description of the attendant discomforts and risks to be expected, if any.

3. A description of the benefits to be expected.

4. A disclosure of appropriate alternative procedures that would be advantageous for the subject.

5. An offer to answer any inquiries concerning the procedures.

6. Freedom to withdraw consent and discontinue participation in the project at any time.

I certify that the subject at the time of giving consent, was mentally capable of doing so, and gave consent voluntarily, without force, duress, or persuasion.

Witness	Person Obtaining the Consent
Date	Date